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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/461,829	12/15/99	ENZERINK	R 265280-64723

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QM32/0131

EXAMINER

PELLEGRINO, B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 01/31/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**



# Office Action Summary

Application No.

09/461,829

Applicant(s)

ENZERINK ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 16-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 35 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.



## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 16-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

### ***Specification***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodell (3176316). Fig. 1 teaches a graft 12 having a proximal and distal end with sutures 16 attached at both ends. Bodell teaches that the graft material is synthetic, col. 3, lines 14-16. However, Bodell does not teach to preserve the graft and place in sterile packaging. It is well known in the art to preserve implantable prosthetic grafts in sterile packaging for purposes of using in a surgery at a later time. It would have been obvious to one of ordinary skill in the art to place the prosthetic graft of Bodell in a sterile package such that it can be used in a surgical procedure at a later time.



Claims 1-3, 5, 7, 10, 11, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder (5671695). Fig. 1 teaches a replacement ligament 12 with a graft made of a tendon 18 and has a proximal and a distal end each with bone plugs (14, 16) secured thereto. It can also be seen that the sutures (24, 26) extend completely through the bone plug. Figs. 6 and 7 teach that interference screws (66, 74) are included in a "kit" which is used for replacement of a ligament. However, Schroeder fails to teach preserving the replacement ligament and placing it in a sterile package. It is well known in the art to preserve implantable prosthetic grafts in sterile packaging for purposes of using in a surgery at a later time. It would have been obvious to one of ordinary skill in the art to place the prosthetic graft of Schroeder in a sterile package such that it can be used in a surgical procedure at a later time.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmieding (5415651). Fig. 12 teaches suture 59 secured to the bone plug 42 and end of the tendon 46. Schmieding teaches to use a semitendinosus tendon for the graft material and that the graft can be formed into a bundle, col. 4, lines 48-56. Schmieding also teaches that long strand sutures can be placed on the graft to aid in placement of the graft in a patient, col. 5, 25-32. The bone plugs at each end of the tendon are secured to the tendon by sutures, which extend completely through the bone plug as seen in Fig. 15. However, Schmieding fails to teach preserving the replacement ligament and placing it in a sterile package. It is well known in the art to preserve implantable prosthetic grafts in sterile packaging for purposes of using in a surgery at a later time. It would have been obvious to one of ordinary skill in the art to place the prosthetic graft of Schmieding in a sterile package such that it can be used in a surgical procedure at a later time.



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Claims 1-5, 7, 10, 11, 12, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seagrave, Jr. (5234435). Fig. 10 shows a replacement graft formed from a patellar tendon, col. 3, lines 61-62. It can be seen that the graft is made of a bundle of strands 48 and has bone plugs (54, 56) secured at each end. The replacement ligament also contains sets of long strand sutures at the two ends to aid in placement of the graft. Fig. 11 teaches to include a fixation screw 60 in the "kit" that is used for replacing a damaged ligament. However, Seagrave, Jr. fails to teach preserving the replacement ligament and placing it in a sterile package. It is well known in the art to preserve implantable prosthetic grafts in sterile packaging for purposes of using in a surgery at a later time. It would have been obvious to one of ordinary skill in the art to place the prosthetic graft of Seagrave, Jr. in a sterile package such that it can be used in a surgical procedure at a later time.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmieding in view of Prewett et al. (5507810). Schmieding is explained as above. However, Schmieding fails to teach a preservation method for packaging the graft. Prewett et al. teach that implantable graft tissues can maintain their mechanical strength by freezing or lyophilizing the graft when packaged, col. 6, lines 31-45. It would have been obvious to one of ordinary skill in the art to package the graft of Schmieding and use the teaching of Prewett et al. that preservation by freezing or lyophilizing the graft material it can maintain its strength when placed in a sterilized package for future use.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino  
January 25, 2000

*Brian E. Pellegrino*



Bruce Snow  
Primary Examiner  
TC 3700, AU 3738